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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/587,662	06/05/2000	Jessie L.-S. Au	JAG-004	8925
266	7590	03/09/2004		
MUELLER AND SMITH, LPA			EXAMINER	
MUELLER-SMITH BUILDING			LEWIS, PATRICK T	
7700 RIVERS EDGE DRIVE				
COLUMBUS, OH 43235			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/587,662	AU ET AL.	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 December 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-24,26-28,33-35,42-47 and 90-126 is/are pending in the application.
- 4a) Of the above claim(s) 33-35,94-96 and 99-101 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3-24,26-28,42-47,90-93,97,98 and 102-126 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 94-96 and 99-101 and currently amended claims 33-35 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicant elected the invention of Group I drawn to a method for inhibiting or reducing cell growth/cancer by administering a telomere damage-inducing agent and a telomerase inhibitory agent. Applicant has further elected species wherein the telomere damage-inducing agent is paclitaxel and wherein the telomerase inhibitory agent is a nucleoside or nucleotide analog. Claims 33-35 are drawn to a method of screening a candidate effective for inhibiting or reducing the growth of an aberrant cell. Claims drawn to screening methods were restricted in the Office Action dated September 9, 2002 (Groups II and VI). Newly submitted claims 94-96 and 99-101 are drawn to methods wherein the telomere damage-inducing agent is an agent other than paclitaxel.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 33-35, 94-96, and 99-101 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant's Response dated December 29, 2003

2. In the Response filed December 29, 2003, claims 1, 3-6, 9-14, 16, 18, 20, 22-24, 28, 33-34, 42, 44-45, and 91-92 were amended; claims 2, 25, 29-32, 36-41, and 48-96 were canceled; and claims 93-126 were added.
3. Applicant presented arguments directed to the rejection of claims 1, 3-24, 28, 33-35, and 42-45 under 35 U.S.C. 112, first paragraph; the rejection of claims 1, 3-4, 8-10, 12-14, 16, 18, 20, 22-24, 26, 33-35, and 42-46 under 35 U.S.C. 102(b) as being anticipated by Gill US 5,756,537 (Gill); and the rejection of claims 1, 3-4, 7-24, 26-28, 42, and 44-47 under 35 U.S.C. 103(a) as being unpatentable over Gill US 5,756,537 (Gill) in view of the Merck Index (1996), 7117, 8958 and 10252 (Merck).
4. Claims 1, 3-24, 26-28, 33-35, 42-47, and 90-126 are pending. Claims 33-35, 94-96, and 99-101 are drawn to a nonelected invention/species. An action on the merits of claims 1, 3-24, 26-28, 42-47, 90-93, 97-98, and 102-126 is contained herein below.
5. The rejection of claims 1, 3-24, 28, and 42-45 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in the Office Action dated July 7, 2003. The rejection of claims 33-35 has been rendered moot in view of applicant's amendment dated December 29, 2003.
6. The rejection of claims 1, 3-4, 8-10, 12-14, 16, 18, 20, 22-24, and 42-46 under 35 U.S.C. 102(b) as being anticipated by Gill US 5,756,537 (Gill) is maintained for the reasons of record set forth in the Office Action dated July 7, 2003. The rejection of

claims 40-41 has been rendered moot in view of applicant's amendment/arguments dated December 29, 2003.

7. The rejection of claims 1, 3-4, 7-24, and 42-47 under 35 U.S.C. 103(a) as being unpatentable over Gill US 5,756,537 (Gill) in view of the Merck Index (1996), 7117, 8958 and 10252 (Merck) is maintained for the reasons of record set forth in the Office Action dated July 7, 2003. The rejection of claims 40-41 has been rendered moot in view of applicant's amendment/arguments dated December 29, 2003.

Objections/Rejections of Record Set Forth in Office Action dated July 7, 2003

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1, 3-24, 28, and 42-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the reduction of telomere length and treatment of cancer related to human breast MCF-7 cells, pharynx FaDu cells, prostate PC3 cells and ovarian SKOV3 cells using a combination of paclitaxel and AZT or d4T, does not reasonably provide enablement for inhibiting or reducing the growth of a cell or for treating cancer using a combination of paclitaxel and a nucleoside or nucleotide analog other than AZT or d4T. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant submitted a Declaration from one of the inventors, Dr. Au, that states, in part, that one skilled in the art can determine without undue experimentation which analog possess inhibitory ability.

The declaration under 37 CFR 1.132 filed December 29, 2003 is insufficient to overcome the rejection of claims 1, 3-24, 28, and 42-45 based upon the insufficiency of disclosure under 35 U.S.C. 112, first paragraph as set forth in the last Office action because: the declaration fails to set forth facts establishing the predictability with regard to the properties of the nucleoside and nucleotide analogs needed to perform the methods as instantly claimed. It is not readily apparent which nucleoside or nucleotide analog or derivative would be effective in the inhibition of telomerase without undue experimentation, as the art failed to establish a correlation between known inhibitors or antiviral reverse transcriptase and telomerase. The specification is not considered to have sufficient disclosure to enable the scope of the present claims and is merely considered an invitation to experiment.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which it pertains to make and use the invention as of its filing date, *In re Glass*, 181 USPQ 31; 492 F2.d 1228 (CCPA 1974). A broad claim requires a correlative broad and sufficient disclosure to support it. There is nothing inherently wrong with defining some part of an invention in functional terms; however, a functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. Examples and description

should be of sufficient scope as to justify the scope of the claims. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula.

10. Claims 1, 3-4, 8-10, 12-14, 16, 18, 20, 22-24, 26, and 42-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Gill US 5,756,537 (Gill).

Applicant's arguments filed December 29, 2003 have been fully considered but they are not persuasive.

Applicant argues: 1) the art use of paclitaxel in combination with telomerase inhibitors is simply a coincidence of treating two distinctly different diseases and does not enable an improved treatment of cancer; 2) Gill fails to show an improved or synergistic therapeutic response; and 3) the prior art does not provide an AZT treatment schedule to enhance the efficacy of paclitaxel.

Arguments presented by applicant are not germane as the invention in question is not drawn to a method of treatment but rather to a method of inhibiting or reducing the growth of a cell comprising administering a telomere damage-inducing agent and a teleomerase inhibitory agent to the cell. Gill discloses the concurrent administration of paclitaxel and AZT for the treatment of Kaposi's sarcoma (KS). The disclosure of Gill is seen to embrace methods contacting cells with a telomere damage-inducing agent and a teleomerase inhibitory agent as required by the instant claims.

11. Claims 1, 3-4, 7-24, and 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill US 5,756,537 (Gill) in view of the Merck Index (1996), 7117, 8958 and 10252 (Merck).

Applicant's arguments filed December 29, 2003 have been fully considered but they are not persuasive.

Applicant argues that Gill does not teach using AZT to enhance the antitumor activity of paclitaxel and therefore, does not teach how to find an AZT dose that can synergize with paclitaxel.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., enhanced antitumor activity of paclitaxel using AZT (synergy)) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Objections

12. Claim 28 is objected to because of the following informalities: the phrase "any one of claims 1" should be amended to more clearly set forth claim dependency. Appropriate correction is required.

13. Claim 43 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 42 is drawn to a method of treating cancer in a patient. The additional requirement of "identifying a patient having cancer" is not seen to limit the independent claim which requires the patient to have cancer.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 93, 97-98, and 102-123 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the reduction of telomere length and treatment of cancer related to human breast MCF-7 cells, pharynx FaDu cells, prostate PC3 cells and ovarian SKOV3 cells using a combination of paclitaxel and AZT or d4T, does not reasonably provide enablement for inhibiting or reducing the growth of a cell or for treating cancer using a combination of paclitaxel and a nucleoside or nucleotide

analog other than AZT or d4T. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below in *In re Wands* USPQ2d 14000. A conclusion of lack of enablement means that, based on the evidence regarding a fair evaluation of an appropriate combination of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention.

These factors include

- (1) quantity of experimentation necessary,
- (2) the amount of guidance presented,
- (3) the presence or absence of working examples,
- (4) the nature of the invention,
- (5) the state of the prior art,
- (6) the predictability of the art and
- (7) the breadth of the claims.

With regard to factors (1) and (2) cited above, undue experimentation is required to determine which nucleoside or nucleotide analog would be useful as a telomerase inhibitor to use for inhibiting or reducing the growth of a cell or for treating cancer for which the instant invention is applicable. There has not been provided adequate guidance in the written description for accomplishing such, as only two different

nucleoside analogs were assessed, out of the numerous nucleoside and nucleotide analogs known in the art.

With regard to factors (4), (5) and (6), it is noted that there is a great deal of unpredictability in the art. For example, various nucleoside and nucleotide analogs are known as inhibitors of polymerases such as reverse transcriptase, however, not all nucleoside and nucleotide analogs are inhibitors of polymerases. Further, there is no discernable pattern as to which nucleoside and nucleotide analog will inhibit a specific polymerase, such as reverse transcriptase, and in particular telomerase. See for example Pai et al., Cancer Research, May 1998, 58, 1909-1913 (X); and STRAHL et al., Molecular and Cellular Biology, 1996, 16, 53-56 (Y). Pai teaches that 3'-azido-3'-deoxythymidine triphosphate is much more inhibitory than 2',3'-dideoxy-2',3'-didehydrothymidine triphosphate, and the cytidine analog ddCTP was not inhibitory. See abstract. STRAHL teaches that prolonged passaging in arabinofuranyl-guanosine, dideoxyinosine (ddl), dideoxyadenosine (ddA), didehydrothymidine (d4T), or phosphonoformic acid (foscarnet) did not cause reproducible telomere shortening, whereas telomerase activity was inhibited by ddGTP and AZT triphosphate. The art at the time the invention was made fails to establish predictability with regard to the properties of the nucleosides and nucleotides analogs needed to perform the methods as instantly claimed. The specification is not considered sufficient disclosure to enable the scope of the present claims and is merely considered an invitation to experiment.

With regard to factors (3) and (7), it is noted that while there are some working examples of compositions comprising AZT or d4T, it is not seen as sufficient to support

the breadth of the claims. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery not how to find out how to use it for themselves. See *In re Gardner et al.* 166 USPQ 138 (CCPA 1970).

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 23-24, 28, 44-45, 90-92, 122-123, and 126 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "derivative" and "nucleoside analog" render all claims in which they appear indefinite wherein the modifications to the structural core are not clearly set forth. In the absence of distinct modifications to the chemical core claimed or distinct language to describe the structural modifications or the chemical names of modified compounds of this invention, the identity of said modified compounds would be difficult to describe and the metes and bounds of said modified compounds applicant regards as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

The term "subtherapeutic dose" has not been clearly defined. No "therapeutic dose" is set forth serving as a standard from which a "subtherapeutic dose" can be ascertained. It is also noted that the claims in which said term appears are drawn to a method of inhibiting or reducing the growth of a cell. While the examiner acknowledges that inhibiting or reducing certain types of cell growth results in a therapeutic effect, the

invention is not limited to "treatment". Furthermore, it is unclear what specific condition(s) is/are being treated.

The phrase "in a dose that produces at least about 20 micromolar plasma concentration in a subject" renders claims in which it appears indefinite. There is nothing inherently wrong with defining some part of an invention in functional terms; however, a functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. In the instant case applicant has failed to set forth what the dosage "is". It would be impossible for one of ordinary skill in the art to be apprised of the scope of the instantly claimed method without trial and error experimentation.

The phrase "the ratio of the AZT concentration to the telomere damage-inducing agent concentration is about 40:60 of their respective therapeutic doses" renders claims in which it appears indefinite. The therapeutic dosage of AZT has not been set forth in the claims. It is also noted that the claims in which said term appears are drawn to a method of inhibiting or reducing the growth of a cell. While the examiner acknowledges that inhibiting or reducing certain types of cell growth results in a therapeutic effect, the invention is not limited to "treatment". Furthermore, it is unclear what specific condition(s) is/are being treated.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 93, 97-98, 102-103, 107-109, 111-113, 115, 117, 119, and 121-123 are rejected under 35 U.S.C. 102(b) as being anticipated by Gill US 5,756,537 (GILL).

GILL discloses in Example 6 that paclitaxel can be administered concurrently with AZT for the treatment of Kaposi's sarcoma (KS). See in particular, col. 9, lines 40-42. GILL further discloses that paclitaxel can be administered orally, via inhalation, intravenously, intramuscularly, intradermally, intraperitoneally, and subcutaneously using various carriers (col. 5, line 19 to col. 6, line 4).

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

22. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

23. Claims 6, 26-28, 90-93, 97-98, 102-103, 105-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill US 5,756,537 (Gill) in view of the Merck Index (1996), 7117, 8958 and 10252 (Merck) and Cheng et al. US 5,869,461 (Cheng).

Applicant claims methods for inhibiting or reducing the growth of a cell or for treating cancer by administering paclitaxel and a nucleoside or nucleotide analog such as AZT or d4T, either serially or concurrently. Further, Applicant claims the methods wherein either each or both of the active agents are administered locally, systemically or regionally. Applicant also claims the methods wherein either each or both of the active agents are administered as a time-release formulation. Finally, Applicant claims methods wherein one of the agents can be administered in sub-therapeutic dosages.

As set forth supra, GILL teaches in Example 6 that paclitaxel is administered concurrently with AZT for the treatment of Kaposi's sarcoma (KS). See in particular, col. 9, lines 40-42. GILL also teaches in that same section that other antiretroviral agents can be used in combination with paclitaxel. GILL further discloses that paclitaxel can be administered orally, via inhalation, intravenously, intramuscularly, intradermally, intraperitoneally, and subcutaneously using various carriers (col. 5, line 19 to col. 6, line 4).

GILL does not explicitly teach that the agents can be administered serially rather than concurrently. GILL does not explicitly teach the dosage of the nucleoside or nucleotide analog. GILL also does not teach that d4T in particular can be administered rather than AZT.

THE MERCK INDEX teaches that stavudine (d4T) is a reverse transcriptase inhibitor for the treatment of an HIV infection. See entry no. 8958.

CHENG teaches that the administration of AZT, because of its potency, is generally 5 mg/kg to about 50 mg/kg per day (column 10, lines 21-31).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use another known anti-HIV agent similar to AZT, such as d4T, in combination with paclitaxel, as GILL teaches that other antiretroviral agents are viable for the treatment of Kaposi's sarcoma. A skilled artisan would have been motivated to use any known antiviral agent for the treatment of HIV concurrently or serially with paclitaxel for the treatment of HIV-related Kaposi's Sarcoma, as such regimes would be useful both in the treatment of Kaposi's Sarcoma and in the treatment of HIV.

Concurrent and serial treatments are frequently used and very well known in the art pertaining to viral and cancer therapeutics. Therefore, methods regarding various dosage regimens and modes of administration are considered a choice of experimental design, and are well within the purview of the prior art

Conclusion

24. Claims 1, 3-24, 26-28, 33-35, 42-47, and 90-126 are pending. Claims 33-35, 94-96, and 99-101 are drawn to a nonelected invention/species. Claims 1, 3-24, 26-28, 42-47, 90-93, 97-98, 102-126 are rejected. No claims are allowed.

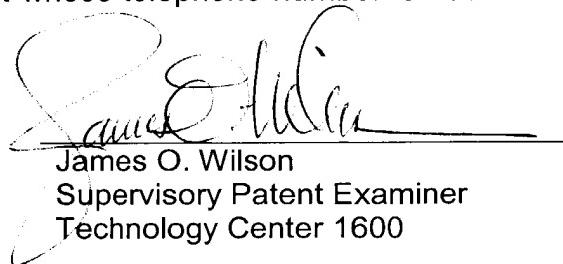
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623


James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

ptl
March 8, 2004